

External Quality Assessment Scheme

INR, POCT Round 1, 2023

Specimens

Please find enclosed 1 ready for use plasma sample S001, volume 0.3 mL. Sample is suitable for Coagucheck, Siemens Xprecia and i-Stat meters.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

INR

Storage and use

Please analyse sample immediately after it has arrived. If this is not possible, store sample in a refrigerator (+2...+8°C) and analyse as soon as possible.

For CoaguChek and iStat meters handle the sample as a patient sample. For Xprecia meters the sample must be handled as a control sample. When the meter asks for a code, please give the QR code below.



Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S001



2023-05-09

INSTRUCTIONS

Product no. 4335
LQ708323011/SE

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **May 31, 2023.**

Inquiries

EQA Coordinator
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External Quality Assessment Scheme

INR, POCT Round 1, 2023

Specimens

Please find enclosed 1 lyophilized plasma sample S003. Sample is suitable for Eurolyzer meters.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

INR

Storage and use

Please analyse the sample immediately it has arrived. If this is not possible, store sample in a refrigerator (+2...+8°C) and analyse as soon as possible. Before analysing, remove the sample from the refrigerator and allow it to reach room temperature. Open the vial carefully to prevent escape of dried material. Add 1.0 mL of distilled water at room temperature. If you do not have a laboratory pipette, transfer all the volume of distilled water from the enclosed plastic tube into the lyophilized plasma vial. Immediately close the vial and let it stand for about half an hour until all the material is completely dissolved. Invert the vial gently several times in order to dissolve any material adhering to the stopper. Do not shake. Plasma can be stored 4 hours at room temperature. Choose "Ctrl.Plasma" in the sample type menu when performing a measurement.

Result reporting

Please enter the results and methods via LabScala (www.labscale.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S003



2023-05-09

INSTRUCTIONS

Product no. 4337
LQ708323013/AT

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **May 31, 2023.**

Inquiries

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External Quality Assessment Scheme

INR, POCT Round 1, 2023

Specimens

Please find enclosed 1 lyophilized whole blood sample S002. Sample is suitable for MicroINR, Coag-Sense and LumiraDX meters.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

INR

Storage and use

Please analyse the sample immediately after it has arrived. If this is not possible, store sample in a refrigerator (+2...+8°C) and analyse as soon as possible. Let the control blood and the diluent reach room temperature. Please find sample handling instructions from separate page.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S002



2023-05-09

INSTRUCTIONS

Product no. 4338
LQ708323012/SE

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **May 31, 2023.**

Inquiries

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External Quality Assessment Scheme

INR, POCT Round 1, 2023

Specimens

Please find enclosed 1 dried whole blood sample S004. Sample is suitable for LabPad meters.

Caution

Quality control specimens are bovine based, and they do not carry biohazards for human, such as HBsAg or HIVAb but they shall be handled with same care as patient samples, i.e. as potential transmitters of serious diseases.

Examinations

INR

Storage and use

Please analyse the sample immediately after it has arrived. If this is not possible, store the sample in a refrigerator (+2...+8°C) and analyse as soon as possible. Let the sample reach room temperature. This could require up to 60 minutes. Please find sample handling instructions from separate page.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S004



2023-05-09

INSTRUCTIONS

Product no. 4340
LQ708323014/FI

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **May 31, 2023.**

Inquiries

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Labquality Oy

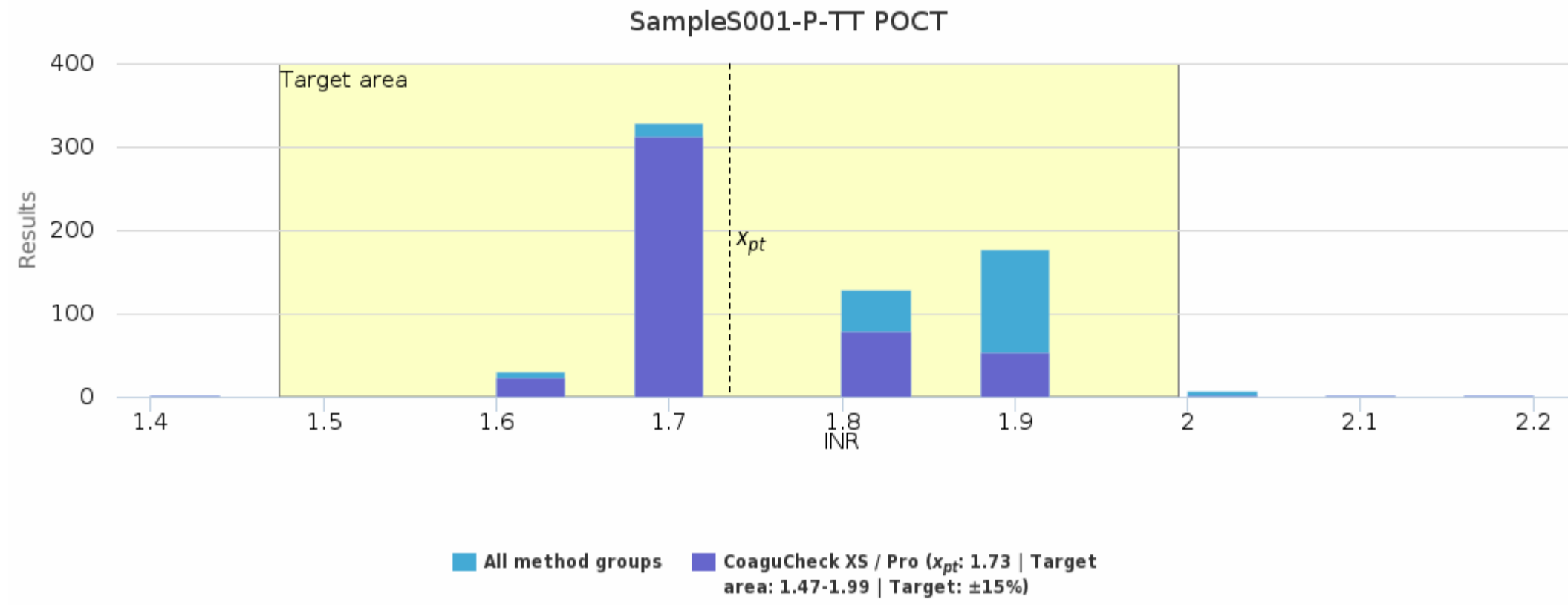
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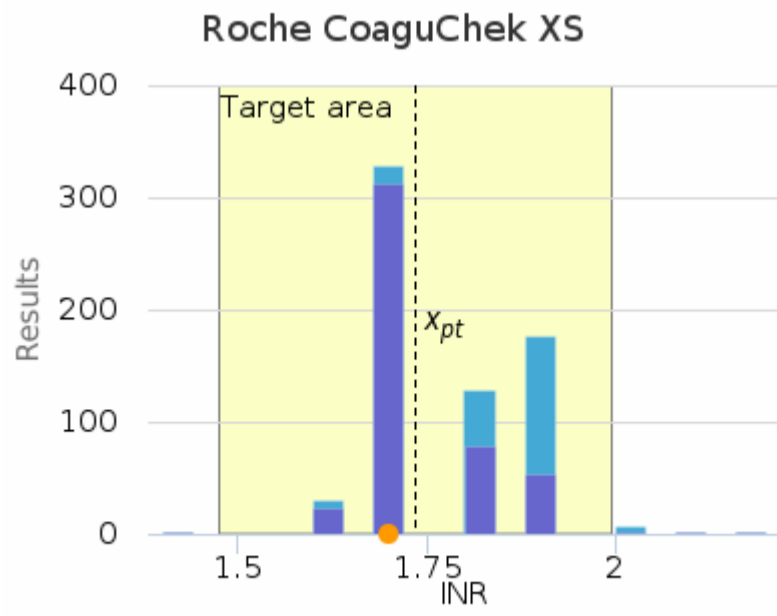
info@labquality.fi
www.labquality.com



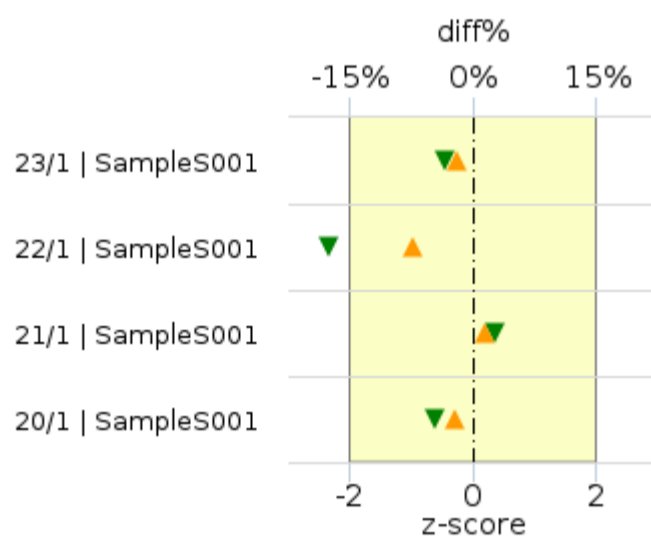
Sample S001|P-TT POCT |CoaguCheck XS / Pro



Sample S001|P-TT POCT |Device specific histograms in LabScala



■ All method groups ■ CoaguCheck XS / Pro
● Own result: 1.70 (01.06.2023)
 Diff%: -2.00 | x_{pt} : 1.73
 Target area: 1.47-1.99 | Target: $\pm 15\%$



▲ diff%
▼ z-score

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S001	1.73	1.70	-2.00%	-0.46
22/1	Sample S001	1.51	1.40	-7.23%	-2.32
21/1	Sample S001	3.65	3.70	1.38%	0.35
20/1	Sample S001	1.23	1.20	-2.27%	-0.62

Report info**Participants**

616 participants from 17 countries.

Report info

Your own result should be compared to others using the same method.

Assigned values (\bar{x}_p , target values) are means of the results where results deviating more than ± 3 standard deviation from the median are removed. The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

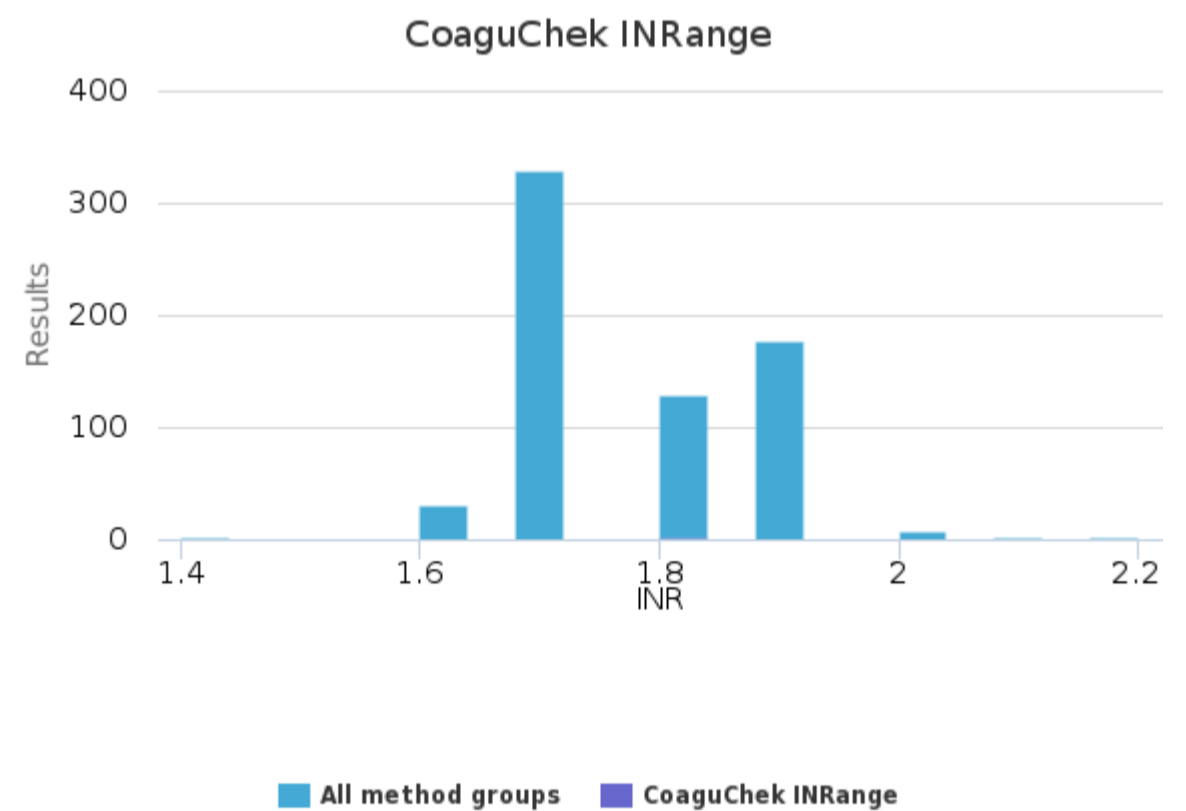
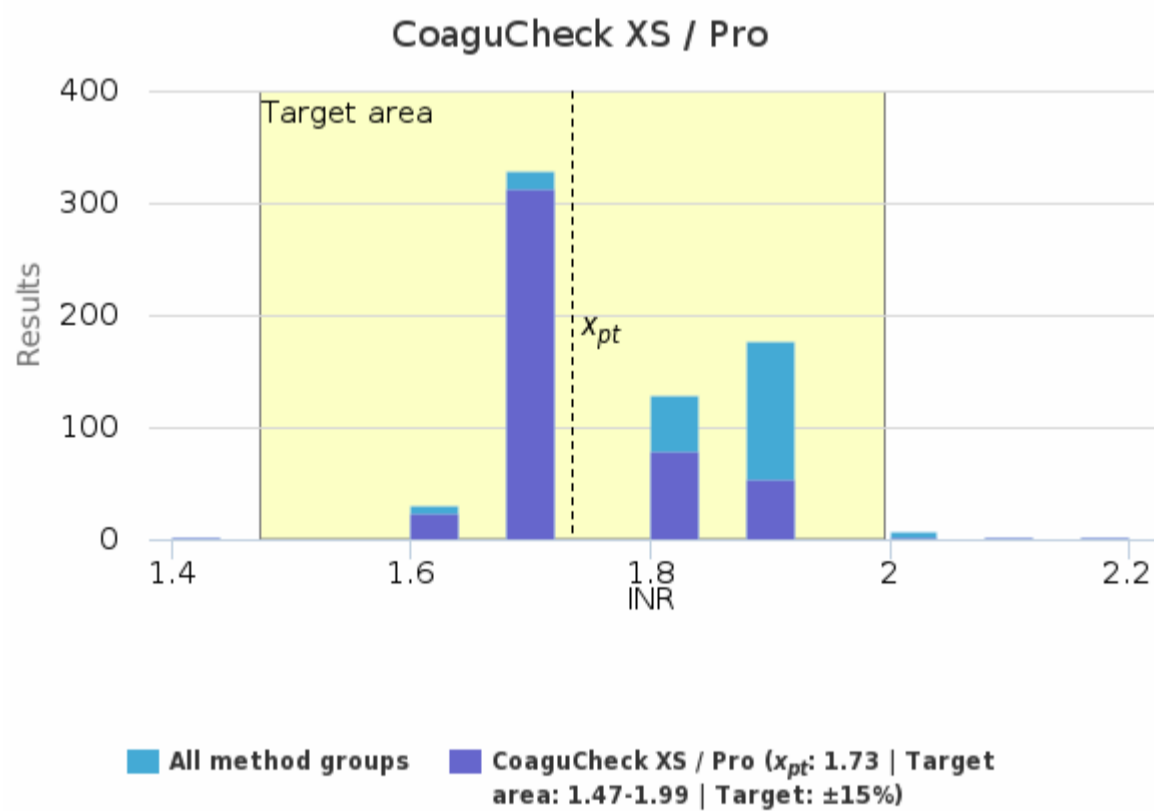
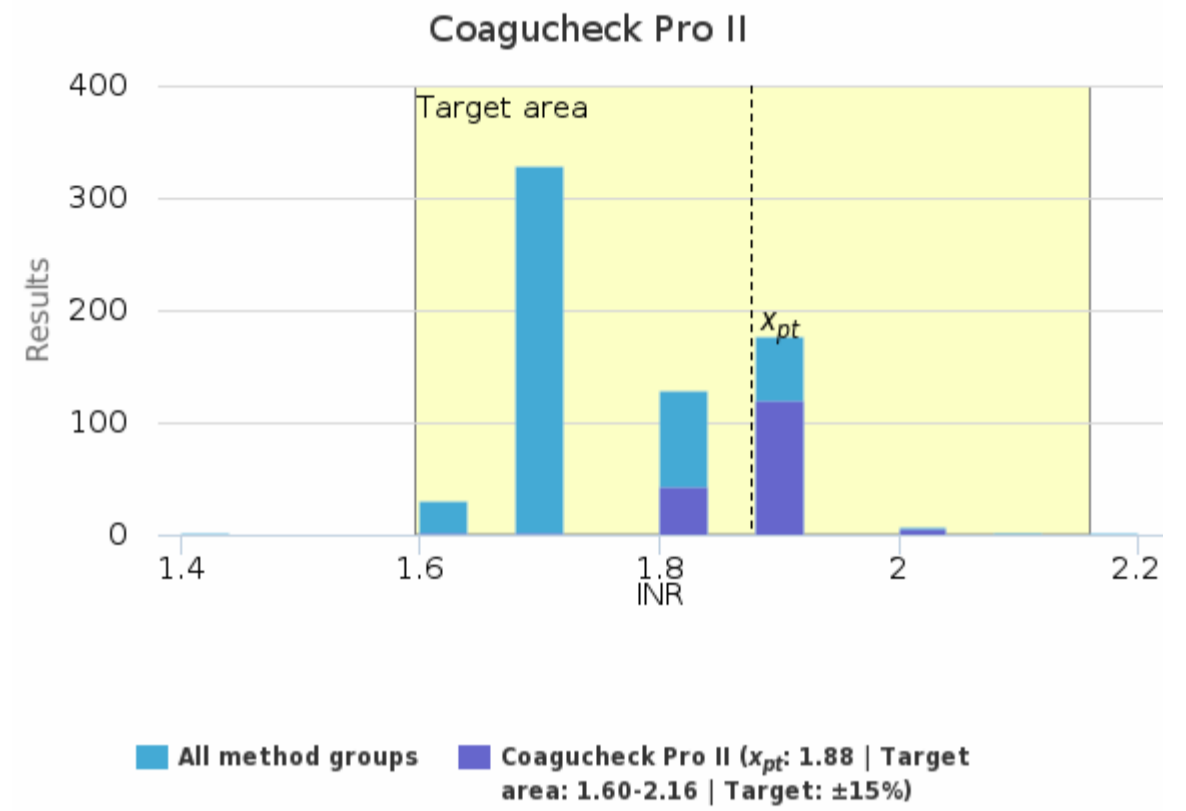
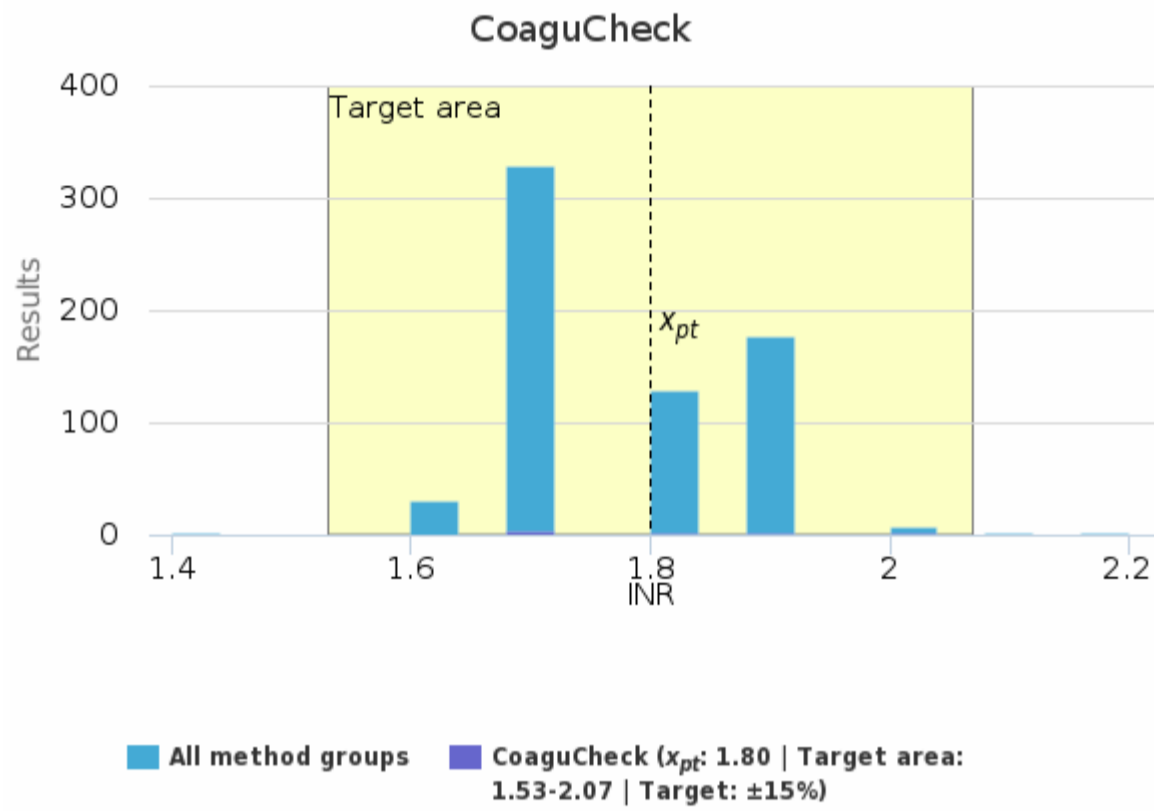
In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method. Results reported with $<$ or $>$ -signs cannot be included in the statistics.

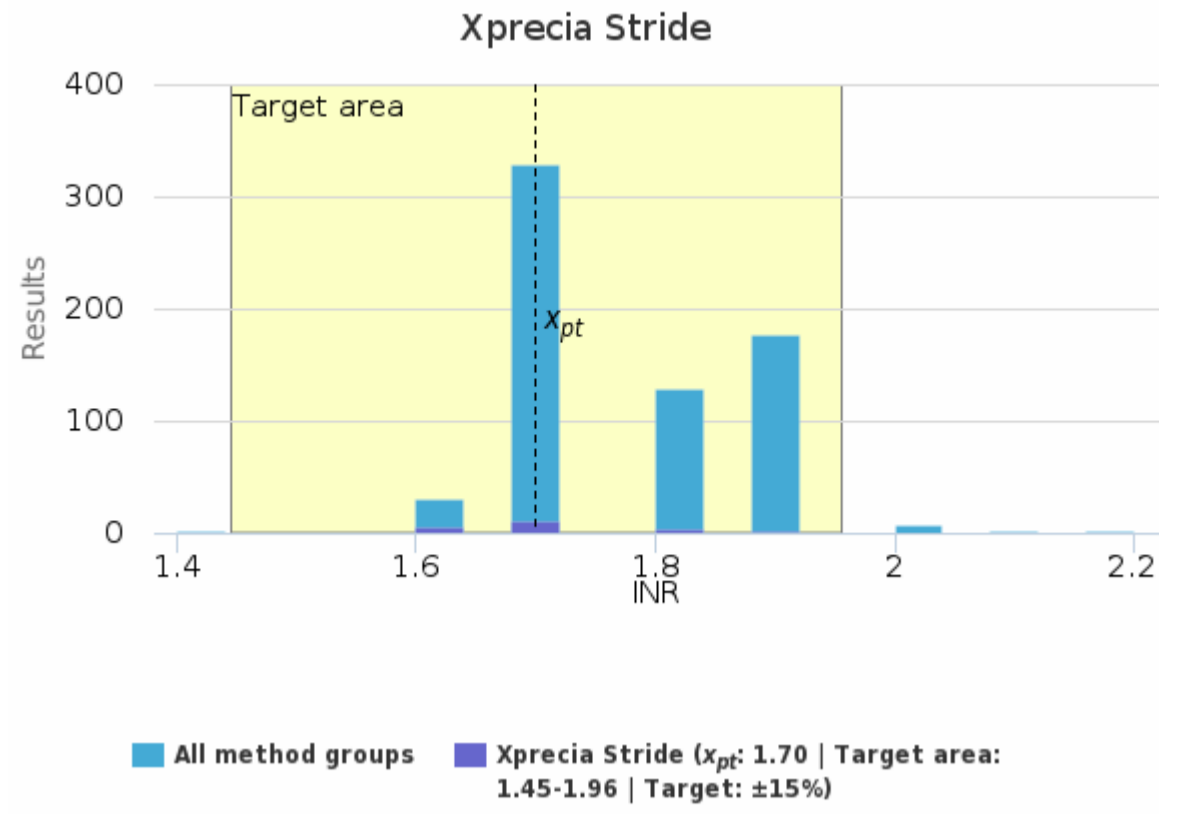
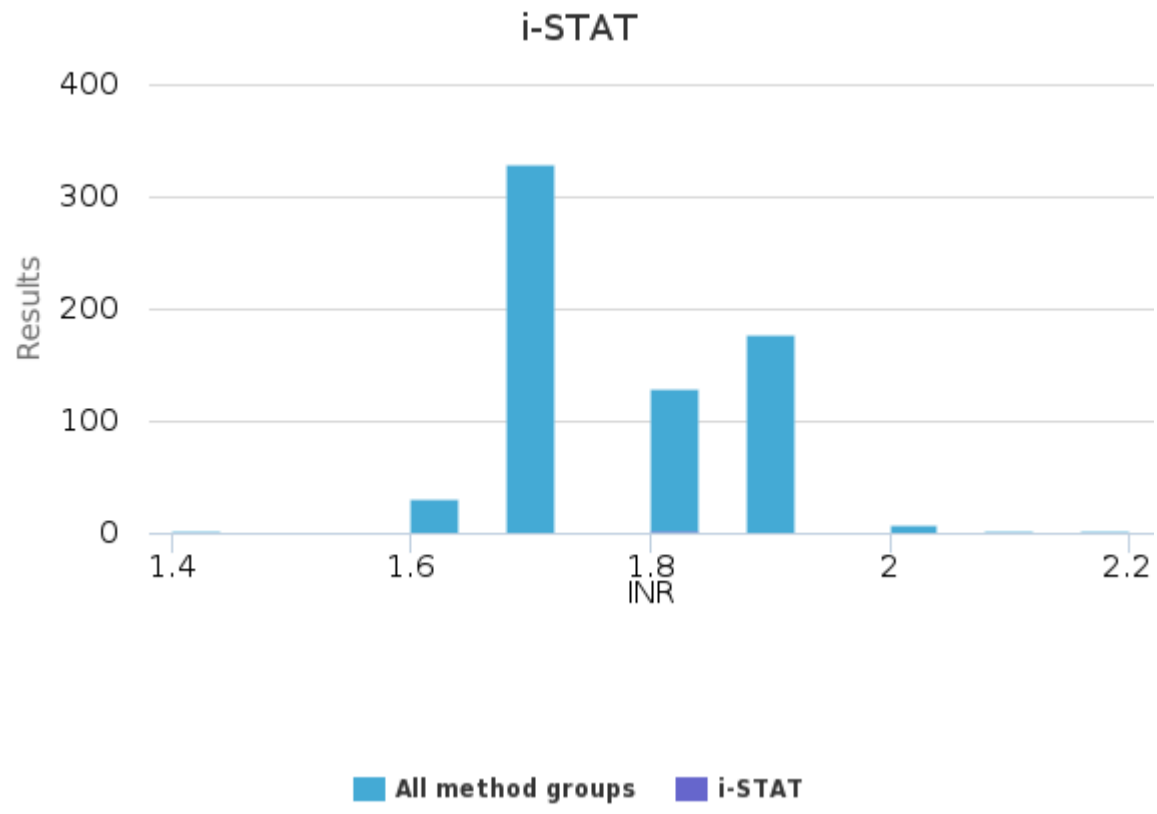
For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

Sample S001 | P-TT POCT, INR

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
CoaguCheck	1.80	1.80	0.11	6.2	0.04	1.70	2.00	-	9
CoaguCheck Pro II	1.88	1.90	0.05	2.6	<0.01	1.80	2.00	2	170
CoaguCheck XS / Pro	1.73	1.70	0.07	4.3	<0.01	1.60	1.90	5	474
CoaguChek INRange	-	-	-	-	-	1.80	1.80	-	1
i-STAT	-	-	-	-	-	1.80	1.80	-	1
Xprecia Stride	1.70	1.70	0.08	4.7	0.02	1.60	1.90	-	20
All	1.77	1.70	0.09	5.2	<0.01	1.60	1.90	11	675

Sample S001 | P-TT POCT, INR| histogram summaries in LabScala

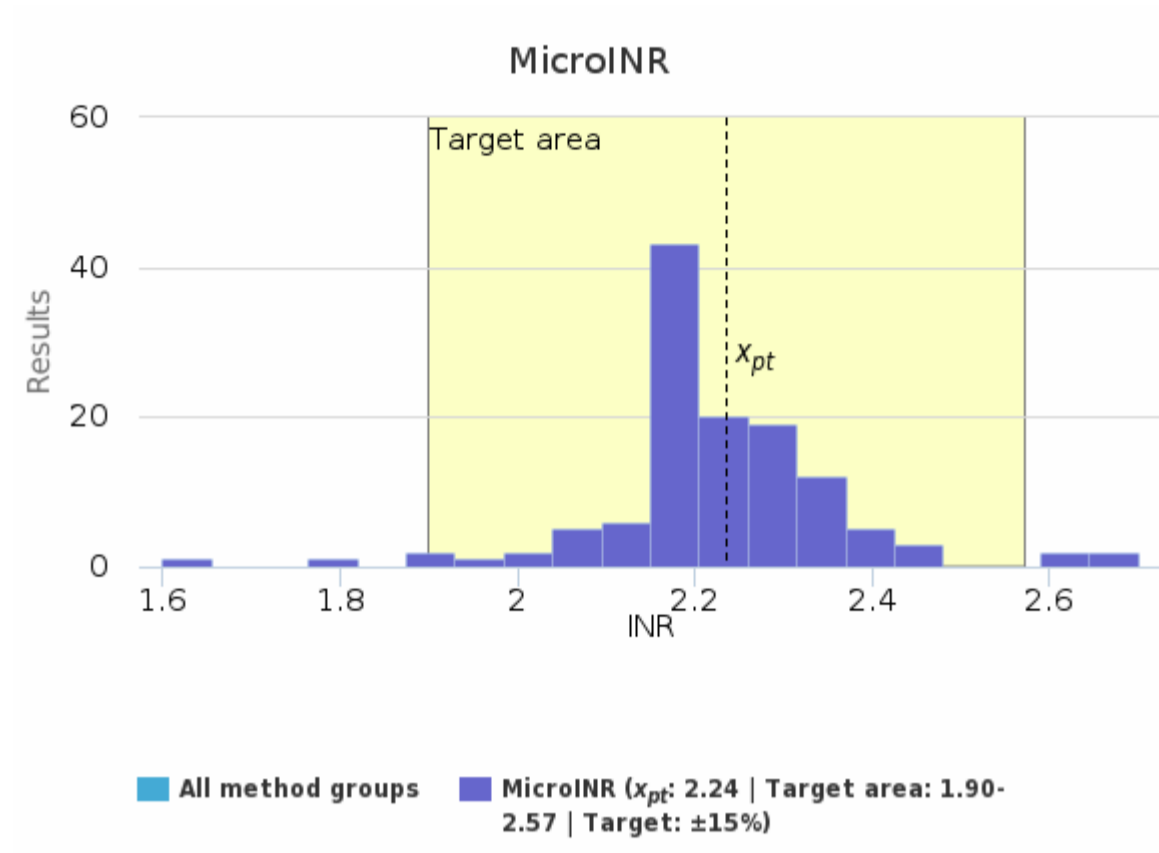




Specimen S002 | P-TT POCT, INR

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
MicroINR	2.24	2.25	0.12	5.5	0.01	1.90	2.65	3	124
All	2.24	2.25	0.12	5.5	0.01	1.90	2.65	3	124

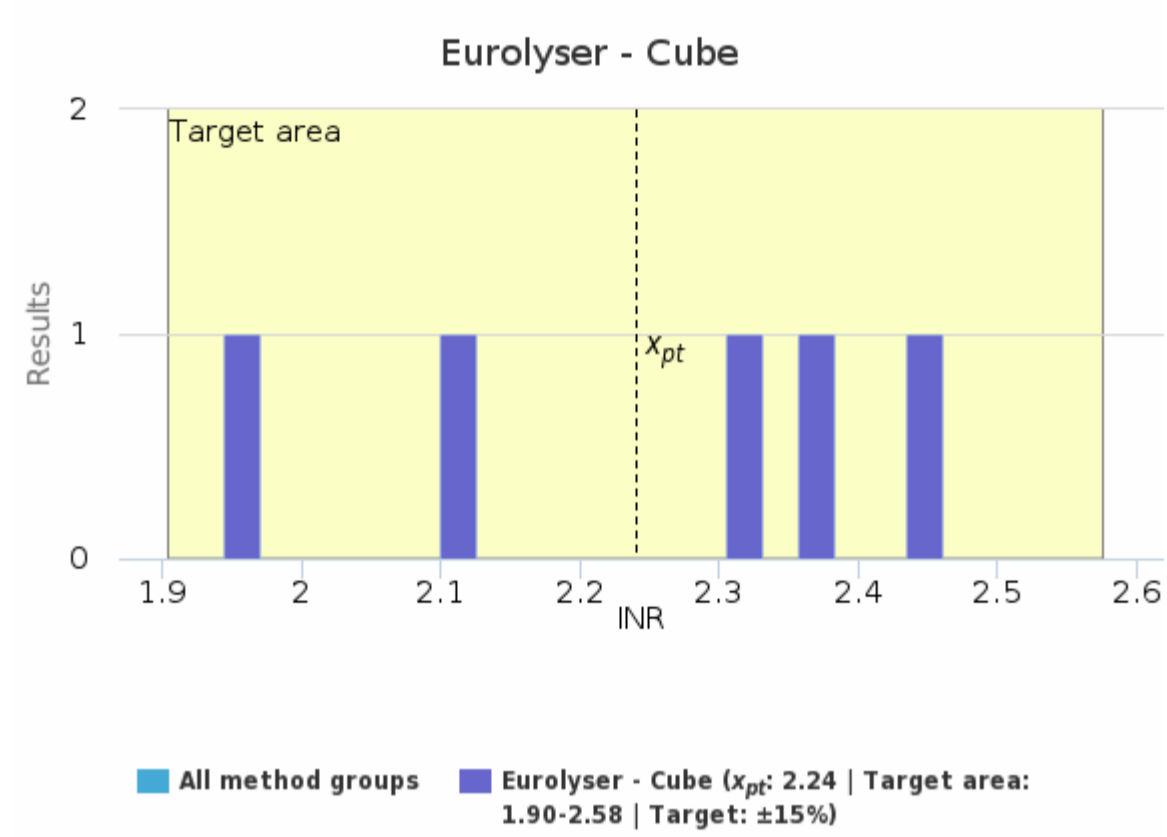
Specimen S002 | P-TT POCT, INR| histogram summaries in LabScala



Specimen S003 | P-TT POCT, INR

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Eurolyser - Cube	2.24	2.33	0.21	9.4	0.09	1.95	2.46	-	5
All	2.24	2.33	0.21	9.4	0.09	1.95	2.46	-	5

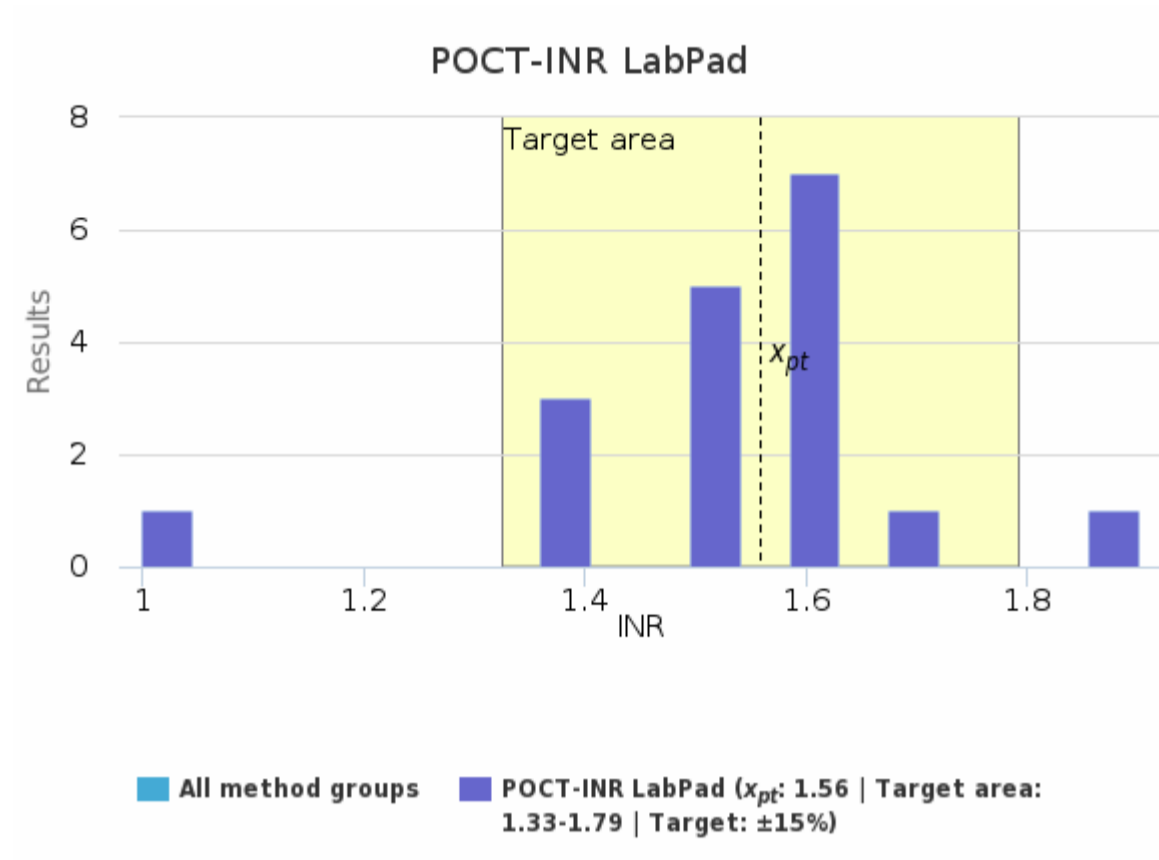
Specimen S003 | P-TT POCT, INR| histogram summaries in LabScala



Specimen S004 | P-TT POCT, INR

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
POCT-INR LabPad	1.56	1.60	0.12	7.9	0.03	1.40	1.90	1	18
All	1.56	1.60	0.12	7.9	0.03	1.40	1.90	1	18

Specimen S004 | P-TT POCT, INR| histogram summaries in LabScala



Report info**Participants**

616 participants from 17 countries.

Report info

Your own result should be compared to others using the same method.

Assigned values (\bar{x}_p , target values) are means of the results where results deviating more than ± 3 standard deviation from the median are removed. The standard uncertainty (u) of

the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method.

Results reported with $<$ or $>$ -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

External Quality Assessment Scheme

INR, POCT Round 1, 2023

Specimens

Sample S001 (LQ708323011) was ready for use plasma suitable for CoaguCheck, Siemens Xprecia and i-Stat meters. Sample S002 (LQ708323012) was lyophilized whole blood sample suitable for MicroINR, Coag-Sense and LumiraDX meters. Sample S003 (LQ708323013) was lyophilized plasma sample suitable for Eurolyzer meters and sample S004 (LQ708323014) lyophilized whole blood sample for LabPad meters.

Based on the previous tests and the results of this round, the samples are homogeneous, stable and suitable for the external quality assessment scheme.

The materials were sent without temperature control packaging.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific histograms and Numerical Summary reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – EQA Coordinator

Sample S001 was intended for CoaguCheck, Siemens Xprecia and i-Stat meters. 5/679 of the results were outside the target area, mean of all results was 1.77.

Sample S002 was for MicroINR, LumiraDx, and Coag-sense meters. All results with exception of three results (n=124) were in the target area. Mean of all results was 2.24.

Sample S003 was intended for EuroLyzer meters, all results were in the target area. Mean of all results was 2.24.

Sample S004 was intended for LabPad meters. 2/18 of the results were outside the target area. Mean of all results was 1.56.

Result outside acceptable limits:

- Please read the meter and strip manual.
- Check that the strips / reagents included in the device are correct and the device is in working order. Check your measurement technique.
- Check and replace strips / reagents that are outdated, wetted, or stored, for example, at the wrong temperature.
- The device's own or unit's internal controls should be used regularly as instructed by the meter manufacturer / laboratory.
- Contact the person in charge at the support laboratory or the device manufacturer.

End of Report

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2023-06-02

FINAL REPORT

Product no. 4335,4337,4338,4340

Samples sent	2023-05-09
Round closed	2023-05-31
Final report	2023-06-02

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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